

**Notice of Allowability**

Application No.

09/670,049

Examiner

Joseph F Murphy

Applicant(s)

MILLER ET AL.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 10/24/2003.
2. ☒ The allowed claim(s) is/are 47-54 renumbered as 1-8.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                     |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>02112004</u> . |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. <u>12092002</u> | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                             |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material                     | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                       |
|  | 9 <input type="checkbox"/> Other   |



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### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kristina Bieker-Brady and Michael Belloveau on 2/11/2004.

The application has been amended as follows:

#### **In the claims:**

47. (Previously presented) A method of producing a population of at least ten cells, wherein at least 30% of the cells are multipotent stem cells substantially purified from skin or tongue tissue of a postnatal mammal or progeny of said multipotent stem cells, wherein said multipotent stem cells are self-renewing, form non-adherent clusters, express nestin, and can differentiate into neuronal and mesodermal cell types, said method comprising the steps of:

- (a) providing skin or tongue tissue from said mammal;
- (b) culturing said skin or tongue tissue under conditions comprising bFGF, EGF or TGF $\alpha$  in which multipotent stem cells proliferate and in which at least 25% of the cells that are not multipotent stem cells die or attach to the culture substrate; and
- (c) continuing culture step (b) until at least 30% of the cells are multipotent stem cells which are self renewing, form non-adherent clusters, express nestin and can differentiate into neuronal and mesodermal cell types, or progeny of said multipotent stem cells.

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48. (Previously presented) A method of producing a population of at least ten cells, wherein at least 30% of the cells are multipotent stem cells substantially purified from skin or tongue tissue of a postnatal mammal or progeny of said multipotent stem cells, wherein said multipotent stem cells are self-renewing, form non-adherent clusters, express nestin, and can differentiate into neuronal and mesodermal cell types, said method comprising the steps of:

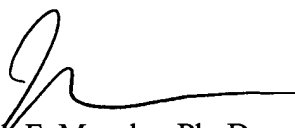
- (a) providing skin or tongue tissue from said mammal;
- (b) culturing said skin or tongue tissue under conditions comprising bFGF, EGF or TGF $\alpha$  in which multipotent stem cells proliferate and in which at least 25% of the cells that are not multipotent stem cells die or attach to the culture substrate;
- (c) separating said multipotent stem cells from said cells that attach to said culture substrate; and
- (d) repeating steps (b) and (c) until at least 30% of the cells are multipotent stem cells which are self renewing, form non-adherent clusters, express nestin, and can differentiate into neuronal and mesodermal cell types, or progeny of said multipotent stem cells.


***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
February 12, 2004

  
YVONNE EYLER, Ph.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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The application has been amended as follows:

#### **In the claims:**

1  
~~47.~~ (Previously presented) A method of producing a population of at least ten cells, wherein at least 30% of the cells are multipotent stem cells substantially purified from skin or tongue tissue of a postnatal mammal or progeny of said multipotent stem cells, wherein said multipotent stem cells are self-renewing, form non-adherent clusters, express nestin, and can differentiate into neuronal and mesodermal cell types, said method comprising the steps of:  
(a) providing skin or tongue tissue from said mammal;  
(b) culturing said skin or tongue tissue under conditions comprising bFGF, EGF or TGF $\alpha$  in which multipotent stem cells proliferate and in which at least 25% of the cells that are not multipotent stem cells die or attach to the culture substrate; and  
(c) continuing culture step (b) until at least 30% of the cells are multipotent stem cells which are self renewing, form non-adherent clusters, express nestin and can differentiate into neuronal and mesodermal cell types, or progeny of said multipotent stem cells.

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48: (Previously presented) A method of producing a population of at least ten cells, wherein at least 30% of the cells are multipotent stem cells substantially purified from skin or tongue tissue of a postnatal mammal or progeny of said multipotent stem cells, wherein said multipotent stem cells are self-renewing, form non-adherent clusters, express nestin, and can differentiate into neuronal and mesodermal cell types, said method comprising the steps of:


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- (c) separating said multipotent stem cells from said cells that attach to said culture substrate; and
- (d) repeating steps (b) and (c) until at least 30% of the cells are multipotent stem cells which are self renewing, form non-adherent clusters, express nestin, and can differentiate into neuronal and mesodermal cell types, or progeny of said multipotent stem cells.


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Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
February 12, 2004

  
YVONNE EYLER, Ph.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600